



*Office of Laboratory Licensure,
Certification & Training*

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Jane Dee Hull, Governor
James R. Allen, MD, MPH, Director

DATE: August 7, 1998
TO: Laboratory Director and QA Manager
FROM: Dr. Barbara J. Erickson, Ph.D., Bureau Chief
SUBJECT: Information Update #49
NOTE: If any problems occur with this web site, please call 1-800-952-0074 or (602) 255-3454 and ask for Technical Resources and Training. Thank You.

1. We are planning on a series of 3 workshops over two days on September 21 and 22, 1998. These workshops will be held in Phoenix, Arizona. The September 21, 1998 workshop will be "Basic Techniques for Technicians and Entry Level Analysts". On September 22, 1998 there will be two concurrent sessions. Session 1 will be "Preparing Your Laboratory for an External Audit". Session 2 will be on "Performing Internal Audits and Surveillances Within Your Laboratory". In order to finalize this workshop, we need to find out if there is enough interest to make it financially feasible. **Please fax the attached form to us before August 14, 1998 so we can make our final plans. Since registration will be on a first come first served basis you must fax this form to us in order to be registered.** The proposed schedule for the workshop is:

Sep. 21, 1998:

Basic Techniques for Technicians and Entry Level Analysts

Audience: Technicians and Entry Level Analysts (limited to 60 people)

Cost: \$50.00 including lunch

8:30- 9:30am - Introduction: Documentation and Liability

9:30- 9:45am - Break

9:45-11:15am - Basics Techniques

11:15-12:45pm - Lunch

12:45- 2:15pm - Basics Techniques (continued)

2:15- 2:30pm - Break

2:30- 4:00pm - Peer Review

Sep. 22, 1998:

Concurrent session 1: Preparing Your Laboratory for an External Audit

Audience: Experienced analyst and first level supervisors (limited to 60 people)

Cost: \$80.00 including lunch

8:30- 9:30am - Introduction: Documentation and Liability
9:30- 9:45am - Break
9:45-11:15am - Preparing for an External Audit
11:15-12:45pm - Lunch
12:45- 2:15pm - Self Audits and Corrective Actions
2:15- 2:30pm - Break
2:30- 4:00pm - Self Audits and Corrective Actions (continued)

Concurrent session 2: Performing Internal Audits and Surveillances Within Your Laboratory

Audience: Quality Assurance Officers and Laboratory Managers (limited to 15 people)

Cost: \$150.00

8:30- 9:30am - Introduction: Documentation and Liability
9:30- 9:45am - Break
9:45-11:15am - Internal Quality Assurance Audits and Surveillances
11:15-12:45pm - Lunch
12:45- 2:15pm - Internal Quality Assurance Audits and Surveillances (continued)
2:15- 2:30pm - Break
2:30- 4:00pm - Internal Quality Assurance Audits and Surveillances (continued)

Session descriptions:

Documentation and Liability

Differences between civil and criminal trial actions; Personal and corporate liability; Negligence; Protection from liability: the Business Record Hearsay Exemption; Protection from liability: the concept of Respondeat Superior

Basic Laboratory Techniques

Significant figures and rounding; Calculations, including standard concentrations and dilution factors; Use of volumetric flasks and pipettes; Use and calibration of balances, micropipettes; Weighing on a balance; Documentation and labeling; Good laboratory practices; Representative subsampling

Peer Review of Raw Data

Specific items to review; Consistency and sample identification; Transcription errors; Completeness; Manual input and calculations; Good laboratory practices, dating and initials; Batch Quality Control - Precision and accuracy, Frequency and acceptability; Instrument performance - stability, baseline shifts, chromatography; Reasonableness and judgement calls; Miscellaneous checks; Out of control documentation

Preparing for an Audit

The drivers behind audits; The client's concern: Credibility - Measured by job performance, Measured by the on-site audit; The most common deficiencies found in audits; The corrective action system; Documentation - Bringing the QA Plan, SOP's, training records, and MDL studies up to date, Good Laboratory Practices, Chain-of-custody and physical custody; Self audit checklists - Reviewing personnel, Reviewing the

laboratory facility, Reviewing documentation; Preparing staff for the audit - Demeanor, Responding to an auditor

Self - audits and Corrective Actions

Types of audits and documentation; Reviewing the laboratory's Standard Operating Procedure against the method; Documentation - MDLs, PQLs, and reporting limits, Precision and Accuracy, Good Laboratory Practices, SOPs and QA Plans, Training files; Self-auditing checklists - Example handout, Sources for obtaining other checklists; Monitoring Quality Assurance - Use of control charts for monitoring production quality, How to choose a control chart variable, Real-time monitoring, Outliers, Benchmarking; Exercises - Audit preparedness: Acronyms in use, locating information, Review of example documentation; Corrective Action System - Checking deficiencies and corrective actions from previous audits, Corrective action forms and tracking; Data gathering and documentation for decision making

Internal Quality Assurance Audits and Surveillances

Preliminary Decisions - Goal of the audit, Project audits, systems audits, and surveillances, Interactive/consultative/ reviews vs. nonparticipative/compliance reviews; Identifying contractual vs. program/ method specific requirements; Checklists; How to audit without causing major disruptions; Following the paper trail; Observations and using your eyes; Active listening; Asking the right questions and getting the right feedback; Documentation, reports, and corrective actions; Follow up; Practice audit

Workshop Presenters:

Lorraine L. Davis, Owner of Quality by Design (QBD)

With a Bachelor's degree, studies towards a Master's degree, and a Professional Certificate in Quality Management, Ms. Davis has 16 years experience in the environmental field. She is the founder and owner of QBD, where she is responsible for all operations of the company. She has directed the company's growth since 1993 from start up to its current compliment of six full time and part time contracted staff.

Thomas Davis, Principal with QBD

Mr. Davis has a twenty-two year interdisciplinary background that includes a Master's degree, plus environmental and medical laboratory experience. As a principle at QBD since November, 1994, he is responsible for marketing, training and auditing activities, and for the final technical review of projects.

2. Recently the Office of Laboratory Licensure, Certification and Training switched to a voice mail system. If you dial our main number, (602) 255-3454, wait for the system to answer your call and then dial in the extension for the individual you want to speak to. You may also press "0" to speak to an operator. Also, you may call a consultant directly at the phone numbers listed here.
3. If you have any questions regarding the Updates, or if you have any technical questions that need clarification, please call or send [e-mail](#) to Prabha Acharya, Program Manager, Technical Resources and Training at the Laboratory Licensure. A [table of contents](#) to all the Information Updates published is also available.

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